

DEC 23 1986

Department of the Navy  
Chief of Naval Operations, (OP-455)  
Washington, DC 20374-2001

45-23645-01  
030-29462

Dear Commander Mendenhall:

I am pleased to respond to the Navy application for a specific license of broad scope for Navy licensees dated August 14, 1986.

As a result of our review of the application, a visit to RASO and NEHC in Yorktown/Norfolk, Virginia, and our review of the RASO, NEHC, and RSC Standard Operating Procedures we have some questions to be answered and some comments. To proceed with the review of the broad license application we will need a response to the items included in Enclosure 1. Enclosure 2 is our proposed Understandings Between the United States Navy and the United States Nuclear Regulatory Commission. Please review this document and let us know if there is anything we need to discuss whether it be additions, deletions, or word changes. Enclosures 3, 4, 5, and 6 contain comments on the original application and on the RASO, NEHC, and RSC procedures which should be implemented or considered in the future for your operating program.

Upon receipt of your response to the items in Enclosure 1 and comments on Enclosure 2 we will proceed with our review. We anticipate that we should be able to issue a broad license shortly after resolution of these issues.

Sincerely,

Original Signed By  
VANDY L. MILLER

Vandy L. Miller, Chief  
Material Licensing Branch  
Division of Fuel Cycle and  
Material Safety

Enclosures:

1. Items for response
2. Understandings
3. Cmts on application
4. Cmts on RSC SOP
5. Cmts on RASO SOP
6. Cmts on NEHC SOP

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## ITEMS FOR RESPONSE

1. So that we can complete the "Understandings" in Enclosure 2, please identify any Navy licenses that now authorize:
  - a. Incineration of radioactive waste.
  - b. Burial of radioactive waste.
  - c. Possession of critical quantities of special nuclear materials. (NRC plans to restrict Navy use of special nuclear material such that critical quantities are not authorized for any permit or location.)
  - d. Possession of special nuclear materials that require contingency plans.
  - e. Field studies deliberately releasing byproduct material to the environment.
  - f. Outdoor uranium munitions testing.
2. Note Item 10 of Enclosure 2 regarding the requirements that human use of radioactive material must be by a physician. NAVMEDCOMINST 6710.4 should be modified to be consistent with NRC regulations.

Understandings Between the United States Navy (USN)  
and the Nuclear Regulatory Commission (NRC)  
Reached in Developing and Issuing  
USN License No. 45- \_\_\_\_\_ - NA

The understandings presently and mutually agreed upon are:

1. It is the NRC's intent that this license will eventually supersede all other USN licenses. We plan to terminate all other USN licenses and pending licensing actions. However, we will coordinate this effort with the USN to assure a smooth transition. The USN Radiation Safety Committee (RSC) will issue a letter to the USN licensees indicating that their present NRC licenses will be eventually terminated and will be replaced by a temporary USN permit. It is our understanding that the RSC will develop a program to replace these temporary permits with permanent ones within a reasonable time.
2. The USN will periodically update its regulations and procedures to reflect the most current NRC or other applicable regulations.
3. The RSC will maintain a list of those items or "commodities" for which permits are not required under the USN's permit program. This list shall be made available when requested by the NRC. Permits will be issued for Cesium-137 calibration sources. Commodity accountability procedures will be reviewed by the RSC in coordination with the NRC.
4. The RSC will obtain prior NRC approval for any radioactive waste incineration, radioactive waste burial, studies involving deliberate releases of radioactive material to the environment (field testing), or outdoor depleted uranium munitions testing before issuing a permit for these activities. (Authorizations for the currently licensed activities identified in response to Enclosure 1, Item 1, can continue without additional NRC approvals. Due to recent questions raised by NRC, the RSC will not authorize the Naval Ocean Systems Center in San Diego to resume use of plutonium power sources in the ocean without prior approval from NRC.)
5. The RSC will assure that the transportation of licensed material will be in accordance with the NRC's, the Department of Transportation's, and any other agencies' applicable regulations governing the shipment of radioactive materials.
6. Effluent releases of radioactive material to the environment will comply with the NRC's regulations and will be as low as reasonably achievable.

Enclosure 2

7. The NRC reserves the right to conduct inspections of the USN program, including permittees, authorized under this license at times and places it considers appropriate.
8. The NRC will provide guidance and assistance in areas pertinent to the administration of this license, to include technical assistance in those matters where the NRC has special capabilities and technical ability, or where the NRC determines that such assistance is in the best interests of its regulatory program or responsibility.
9. The RSC will not issue any permit authorizing a total possession limit of special nuclear material equal to or greater than critical quantities and will assure that accumulations of special nuclear material will not reach critical mass quantities, as determined by the procedures specified in 10 CFR 150.11(a), at any site or for any permit. (This assumes that in response to Enclosure 1, Item 1, no such licenses are identified.)
10. Human use of licensed material may only be used by, or under the supervision of, physicians as defined in 10 CFR 35.3(b) until April 1, 1987. After April 1, 1987, byproduct material for medical use may be used by, or under the supervision of, physicians, dentists, or podiatrists who meet the training and experience requirements contained in Subpart J, 10 CFR Part 35.
11. The NRC and USN will mutually arrange for Navy inspectors to be sent on inspections of non-Navy licensees with NRC materials inspectors and to attend appropriate NRC training courses.
12. The RSC will establish leak test requirements for sources and devices containing licensed material consistent with NRC regulations and license requirements.
13. The RSC will incorporate NRC's inspection criteria into the USN inspection guides to assure compatibility of inspection programs between the USN and the NRC.
14. The RSC will maintain an adequate level of professional and clerical staffing to carry out its responsibilities under this license.
15. The RSC will coordinate with the NRC staff with respect to any special procedures for notifying NRC of incidents; for example, cases where more than one Region needs to be notified.

## COMMENTS ON APPLICATION

1. Item 9:
  - a. Add the words "and guidelines" after "NRC regulations."
  - b. What criteria will Navy RSC use in determining adequacy of permittee's facilities/equipment?
2. Item 10.a:
  - a. A word appears to be missing after "operations."
  - b. Add "equivalent and" after "maintaining an."
3. Item 10.d: In the last sentence change "as if they were under the" to "in accordance with."
4. Item 10.f: We suggest modifying the first sentence. We assume RSC will review permittee's applications using NUREG-0767. If requested possession limits exceed Table 1 of NUREG-0767 or sum of ratios of requested possession limits equals or is greater than 1, then either (a) possession limits will be reduced, (b) possession in one building will be limited or (c) contingency plan will have to be developed by permittee.
5. Item 10.g: Delete the last three words - "at offsite locations."
6. Item 10.h:
  - a. Add "or guidelines" at end of sentence. Authorizing limits other than NRC established guidelines should not be allowed.
  - b. A slight discrepancy seems to exist between NAVMED P-5055, Chapter 1, article 1-5, item (8) and NAVFACINST 5100.15, II, J.2 concerning release of materials and areas for unrestricted use in that Reg Guide 1.86 is more restrictive. NAVDACINST 5100.15 also seems to conflict with Navy's position on item 10.h of the application.
7. Item 10.i:
  - a. Add reference to tritium bioassay guidelines and change "bioassay guidelines for" to "bioassay requirements for."
  - b. Application states NAVMED P-5055 is consistent with 10 CFR Part 20, i.e., equal or greater than 25% of MPD requires dosimetry. But, DODINST 6055.8, Section F.4, requires personnel dosimetry if person can get greater than 10% of MPD. DOD and Navy instructions seem to be conflicting. Conflict, if real, should be resolved.

Enclosure 3

8. Item 11:

- a. Do any Navy licensees (soon to be permittees) use decay-in-storage for disposal? This is a method not clearly authorized in Part 20. Does this license application imply that decay-in-storage will NOT be permitted?
- b. Note that new burials and new incinerators (if any) must be approved by the NRC.
- c. Add "Requests for disposal pursuant to 20.302, 20.305 or exemptions to disposal requirements will not be authorized without prior NRC concurrence."

9. General comments:

- a. NAVMED P-5055: Note that there is no definition of "restricted area." (See p. 1-5.) Radiation area is defined but means area in which one could receive greater than 5 mrem in any one hour or greater than 100 mrem in 5 consecutive days. NRC regs require certain things for a restricted area when Navy regs/policy do not address these areas.
- b. NAVMED P-5055, Section 4-2(3)(b): This section seems to allow individual Navy permittees to make a local decision to exceed 500 mrem/year.
- c. The situation with Naval Research Laboratory (NRL) should be clarified. NRL does not come under the NAVSEACOM and has been independent of RASO for licensing activities for some time.

## RADIATION SAFETY COMMITTEE SOP

1. Appendix B: Typos in State Codes 57 and 82 - should read "Samoa" and "Philippines."

2. Appendix C: We assume that "Use Codes" 4 through 9 are assigned to Medical Commands and are not really human use (e.g., SNM less than 200 g is NOT used in or on humans). New Part 35 states that "medical" means radioisotopes administered to humans. Instead of groupings titled "Medical Uses" and "All Other Uses" as listed in Appendix C we suggest the codes be grouped as follows:

### MEDICAL USES:

Nuclear Medicine (Limited Scope)  
Nuclear Medicine (Broad Scope)  
Teletherapy

### LABORATORY/RESEARCH/OTHER

Research (Non-human Use)	Type A Broad Scope
Irradiators (Less than 10,000 Ci)	Type B Broad Scope
Navy Drug Screening Lab	Type C Broad Scope
Gas Chromatographs	SNM - Unsealed < Critical Mass
SNM less than 200 Grams	Analytical Measuring Instruments
Other	

### INDUSTRIAL/MILITARY:

Radiography	RTG Power Sources
General Industrial - Not otherwise Coded	Fixed Gauges
Calibrator (Instrument Cal)	Irradiators
Environmental Applications	Buried Waste (NEESA)
Portable Gauges	Source Material
DU Munitions	Navy Wide Commodities
Subcritical Assemblies	Commodities - Handling and Storage

Regardless of the coding assigned, the grouping listed above would facilitate distribution of information from NRC directed to permittees that possess radioactive material for certain uses.

3. Section II.7: Note typo in Section title; numeral 1 is used rather than upper case I.

4. Section II.7.1: This section says a permit may be terminated at the request of the permittee. No mention is made of a need for the permittee to remove/dispose of all radioactive material and to decontaminate the facility to specified levels for unrestricted use.
5. Sections III.4 and III.6: It may be preferable to combine Section III.4 with the first paragraph of Section III.6. In Section III.4 it appears that Commands will have 60 days to correct observed violations, yet this is modified by the first paragraph of Section III.6.



## COMMENTS ON RASO SOP

1. Item 6.a.(3)(f), p. 7: This item should be corrected to indicate that in some cases NRC has jurisdiction outside the geographical United States, i.e., such as at Antarctica.
2. Enclosure (18), Standard Navy Permit Conditions, p. (18)-7: Standard condition 36 should be deleted because this condition is not used in industrial licensing and it provides for an exception to the regulations which only NRC should authorize.
3. Appendix A, item 8, p. A2(15)-2: This item appears to indicate that unqualified radiographers may perform radiography. In the past, Navy has indicated that there will be no radiography assistants on ships. Should this state "lead radiographers"?
4. Appendix A, item 5, p. A3-2: This section shows expected radiation levels outside of an radiography exposure facility when the source is in the center of the facility. If placing the source in the center of the facility is critical to meet these levels, then the operating procedures should clearly require appropriate placement. Note: the operating procedures included do not seem to address operations conducted within the facility.
5. Appendix B, item 6, p. B-1: This item states that when radiography and calibration permits are issued to the same ship, the radiography RSO shall be RSO for the other permit also. While this seems acceptable, the radiography RSO may not have any experience with the calibrator or neutron sources. Perhaps the RSO should have to attend the Radiac Instrument Course or be limited to certain activities similar to those imposed in radiography.
6. Appendix B, item 6, p.B-1: This section also indicates that the ARSO will be from the Radiological Controls Division. What training and experience requirements do they have to meet? It may be appropriate to require either the RSO or ARSO to complete the Radiac Instrument Course (see above).
7. Appendix C, item 7, p. C1-2: The training and experience resumes for the radiography RSO and ARSO do not indicate that they will be qualified radiographers nor have one year experience. The RSO and ARSO should meet minimum NRC guidelines. What minimum training and experience requirements will RASO require?

8. Appendix C, item 7, p. C2-1: Permit applicants should identify radiography training course instructors other than the RSO or ARSO.
9. Appendix C, enclosure 2, p. C2(3)-1: It is unclear if these questions are for the assistants or the radiographers, or if only part I or both parts are for the assistants. If only Part I is for assistants, the questions do not adequately cover operating and emergency procedures.
10. Appendix C, attachment 3, supplemental sheet 5, p.1: Same comments as in Item 4, above.
11. Appendix C, attachment 4, p. C4(3)-1: Why is most of the training program presented in attachment 2 also presented in attachment 4? Also, on p. C4(3)-II-1, while the title indicates that the information is for training radiographer assistants, a course prerequisite which requires 525 hours of on the job experience seems contradictory.
12. Appendix C, item 8.c.(1)(b), p. C4(4)-11: The example cited for allowing radiation levels to exceed 2mr/hr at the restricted perimeter needs to be clarified to indicate that the dose must be determined over the preceding hour to the end of the proposed exposure (this also should be addressed in Appendix A).
13. Appendix D, p. D1-3: Neither the RSO or ARSO in this example application has completed the radiac training course. What minimum training and experience requirements will Navy set?
14. Appendix D, supplemental sheet 3: This sketch shows that radiation levels in unrestricted areas will exceed 100 mr/hr and that long exposures may be conducted at night to calibrate high range dosimeters. Certain access restriction requirements must be met under these circumstances in accordance with Part 20. However, the procedures do not seem to address them. Periodic occupancy checks of buildings and use of environmental TLDs nor simply verifying that no one is outside in the vicinity of the window prior to exposing the source (as required in Appendix D, attachment 4, enclosure (7), item 2.a.(5), p.D4(7)-2) do not seem sufficient.
15. Navy should describe its procedures for ensuring that radioactive commodities which will be possessed and used by non-permitted end users will be properly stored, handled, and disposed.

## COMMENTS ON NEHC SOP

1. Table I: No mention is made of the need for written reports.
2. Table I re: Sections 20.403 and 20.405: Summarization of reporting requirements is not quite accurate (e.g., Section 20.403(a) requires reports re: whole body exposure greater than or equal to 25 rem), or is incomplete (e.g., Section 20.405(a) requires reports for certain exposures of individuals and this is not clear in summarization).
3. Table I: References to 10 CFR Part 35 are for Part 35 as it is today; these will need to be changed after April 1, 1987.
4. Table I re: Section 35.42(a): Does not mention need to report to referring physician, patient, etc.
5. Table I: Does not mention Section 35.43 (report of diagnostic misadministrations) now required to be reported quarterly.
6. Table I: If Navy permittees only "barely" comply with time frames listed in Table I, Part 20, Part 35, etc., how will Navy Committee be able to comply with the actual time constraints in the regulations? (See also comment on Sections IV.1 and IV.2 of RSC SOP)
7. Chapter II, Section 4.d.(2): Based on NRC's long experience doing licensing, the Navy should limit deficiency telephone calls to a few, simple items that can be easily answered. Requests that generate numerous and/or lengthy questions should prompt a deficiency letter, not a call.
8. Chapter III, Section 1: NRC does not have a "required" inspection frequency. Perhaps scope and frequency of inspections will be "consistent with current NRC policy."
9. Chapter III, Section 2.a: Insert the word "Manual" before "Chapter 2800" in first sentence. Change the second sentence to read: "The NRC licenses issued to Naval Medical Commands before the issuance of the single broad Navy license..."
10. Chapter III, Table 3: Change "institute" to "institution" opposite Program Codes 02110 and 02120.
11. Chapter III, Section 2.c: This commitment would appear to be less restrictive than NRC's current practice with respect to current licensees with Program Codes 02110 and 03610.

12. Chapter III, Section 3.a.(4): This section needs to be revised to be consistent with Section 20.105(b)(1) and (2). Unrestricted areas must meet both (1) and (2) of Section 20.105(b).
13. Appendix A, first sample letter: How will suppliers to Navy permittees be notified of the change?
14. Appendix A, second sample letter: What will the information package contain?
15. Appendix A, third sample letter: Change "acknowledge" to "acknowledged" in first sentence.
16. Appendix A, fourth sample letter: Change "issue" to "issuance" in first paragraph and "renewal" to "renewed" in second paragraph.
17. Appendix B, page 2: Correct spelling of "hyphen." Regarding the Use Code: How is this determined, especially in cases in which a license authorizes activities covered by several codes?
18. Appendix B, page 3: Correct spelling of "Crete" with State Code 74 and "Philippines" with State Code 82.
19. Appendix C1: Proposed Revision 2 of Regulatory Guide 10.8 does not clearly indicate to applicants what minimum features, items, commitments, etc., are needed if applicant chooses to submit "equivalent" procedures.
20. Appendix C2: Suggest Navy use reviewer's checklist that is part of the Standard Review Plan for teletherapy.
21. Appendix D1: Comments/observations -
  - Condition 3 might be revised to require permittees to have up-to-date copies of NRC regulations.
  - Condition 4 is equivalent to the current tie-down condition and will not be used, for at least limited scope medical licensees, after April 1, 1987.
  - Condition 11.a is not correct. Physician is defined in 10 CFR 35.3(b) now, and in 10 CFR 35.2 in revised regulation.

- Condition 12: The Navy should consider whether it really needs this condition as a visiting physician provision is in the revised Part 35. If this condition is needed, then Condition 12.c should be revised to read "...by a Nuclear Regulatory Commission or Agreement State license or ..."
- Condition 6 is used by NRC only on hospital-based nuclear pharmacy pacemaker licenses.
- Condition 13: The revised Part 35 permits certain changes and that permission is in Section 35.31, not in Section 35.36.

22. Appendix D2: Comments/observations -

- NRC will prepare a sample teletherapy license and incorporate it in a revision of the Standard Review Plan. The Navy should use the sample license in the current SRP until April 1, 1987 as a model for its teletherapy permits.
- Condition 2: Correct spelling of "entirety."
- Condition 3: Consider changing to require maintenance of up-to-date copies of NRC regulations.
- Why does Appendix D1 not contain a condition similar to Condition 7, Appendix D2?
- Condition 5: Equivalent to current tie-down condition and apparently not to be used after April 1, 1987.
- Condition 10 is equivalent to current visiting physician condition; revised Part 35 contains similar provision. Note that Condition 10 of Appendix D2 is not identical to Condition 12 of Appendix D1 (e.g., Agreement State licenses are recognized in Appendix D1).
- Condition 21: Why is there not an equivalent condition in Appendix D1? Why is reference made only to Part 35? Why not also mention Parts 20, 21, etc?

23. Appendix E: Has not the license for the Naval Health Research Center, San Diego, been terminated? Spelling of "Philippines" should be corrected.

24. Appendix E: Should not Item 10 under Computer Listing read "Radiation Safety Officer's Name and Phone Number"?

25. Appendix F1: Reference to regulations and requirements seem to refer to current Part 35 and not to revised Part 35.

26. Appendix F2:

- ° Item 1a: Should this be consulting physicist, not physician?
- ° References are to current Part 35; need to be changed as of April 1, 1987.
- ° Item 13: Decay calculations for intervals not exceeding 1 month?
- ° Item 13(a)(1)(d): Should read "greater than + or - 5%."
- ° Item 13(b)(2): Spelling of "not" needs to be corrected.
- ° Item 14d: Change "with" to "within."
- ° Item 15a: Spelling of "linear" should be corrected.